Global Medical Device Standards & Their Acceptability for Regulatory Purposes

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Benefits of Standards

Barriers to global trade can be minimized by uniform technical standards

- The World Trade Organization (WTO) encourages use of international standards where they exist[1]

International standards should take precedence over national standards, because international standards can be used to align multiple nation's standards

- Can be used to meet regulatory requirements

Voluntary unless explicitly stated in a regulation (i.e., harmonised symbols in MDR, 13485 in FDA QMSR

1. World Health Organization, Article 20, General Agreement on Tariffs and Trade

Use of Standards

Benefits to use of Standards

- Alignment with regulatory & customer expectations
- Less data and technical documentation needed to be provided to regulatory bodies
- Facilitates procurement & tender processes
- Tried & tested ‘best practices’ help ensure compliance

Implications of not using Standards

- Delays in device approval due to missing features or requirements
- Competitive disadvantage
- Restricts access to markets
- More cost, time and resource
- Decreased user confidence

Standards and

The World Trade Organization's (WTO's) Technical Barriers to Trade Committee[2] defines 'Six Principles' for the development of international standards:

Transparency	Openness	Impartiality and Consensus	Effectiveness and Relevance	Coherence	Development Dimension
Information regarding current work as well as proposals for standards, guides and recommendations under consideration should be accessible to all interested parties	Membership of an international standardizing body should be open on a non-discriminatory basis to relevant bodies	Provision of opportunities to contribute to development of an international standard. Consensus procedures should take into account the views of all parties concerned	International standards need to be relevant and to effectively respond to regulatory and market needs	International standardizing bodies avoid duplication or overlap of work of other international standardizing bodies	Impartiality and openness of standards development to ensure that developing countries are not excluded

2. World Health Organization, Agreement on Technical Barriers to Trade

International Regulatory Forums

There is global agreement that **international consensus standards** are ideally suited to medical device development, manufacture and regulation, supported by:

- International Medical Device Regulators Forum (IMDRF)[3], formerly GHTF

IMDRF International Medical Device Regulators Forum

- Global Harmonization Working Party (GHWP)[4], formerly AHWP

GHWP Global Harmonization Working Party Towards Medical Device Harmonization

Both organisations focus on regulatory convergence around standards

3. IMDRF, www.imdrf.org
4. GHWP, www.ahwp.info

ISO/IEC & CEN/CENELEC Standards

The International Organization for Standards (ISO) & the International Electrotechnical Commission (IEC) have formal working agreements between its European counterparts, CEN & CENELEC:

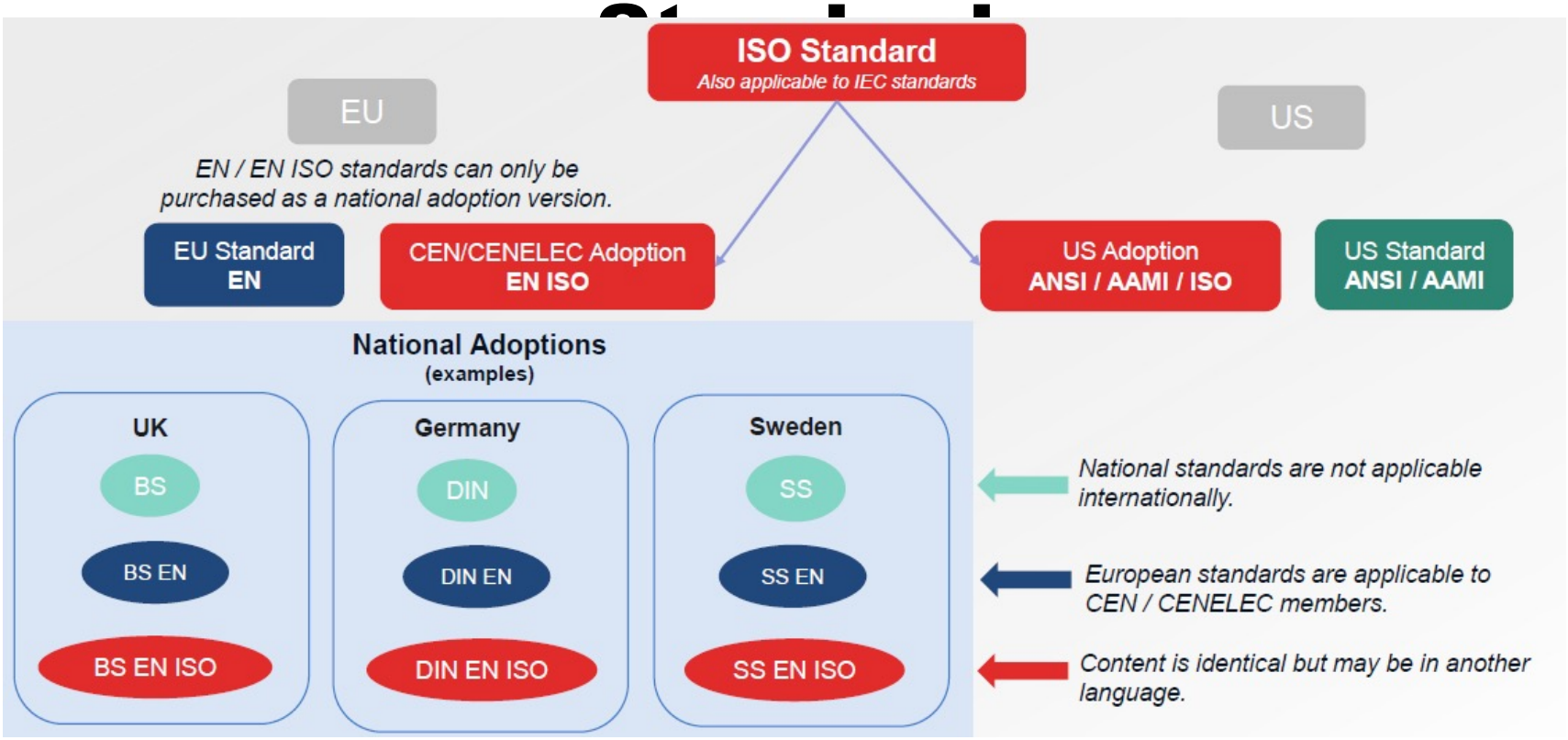
- The Vienna Agreement[5] between CEN and ISO
- Frankfurt (formerly Dresden) Agreement[6] between CENELEC and IEC

These agreements seek to:

- Make best use of available resources
- Increase transparency and cooperation
- **Ensure international standardisation takes precedence over national standardisation**
- Enable parallel approval of standards
- Recognise that European Union may have particular needs

5. Vienna Agreement, ISO/CEN, 1991
6. Frankfurt Agreement, IEC/CENELEC, 2016

Relationship of National & International Standards



Use of European Standards

Informative Z Annexes published in **European standards** as a requirement for harmonisation

Contain specific information required for the application of the relevant EU regulations by **demonstrating how the standard addresses/covers the legal requirements**

Annex Z maps to **MDR 2017/745**

EUROPEAN COMMITTEE FOR STANDARDIZATION

Important for manufacturers who want to demonstrate compliance with the applicable EU regulation as they **provide the 'presumption of conformity' to the requirements of the regulation**

Standards published and subsequently updated with Annexes Z and harmonised are identified with +A11

- This indicates that annexes Z have been added
- Standards published with Annexes Z and subsequently harmonised do not have this amendment

CENELEC

Use of European Standards

Annex ZA
(informative)

Relationship between this European standard and the requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/575 of 14.4.2021 to provide one voluntary means of conforming to the requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Tables ZA.1, ZA.2 or ZA.3 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding requirements of that Regulation, and associated EFTA regulations.

SOURCE: EN ISO 13485:2016+A11:2021

Annex ZA

Table ZA.2 – Correspondence between this European standard and the requirements of Annex IX of Regulation (EU) 2017/745 [OJ L 117]

Requirements of Annex IX of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1	4.1	Partially covered. EN ISO 13485 requires the quality management system to comply with applicable regulatory requirements. EN ISO 13485 is applicable to all sizes of organization and all types and class of medical device. EN ISO 13485 does not have requirements for the quality management system to be subject to third party assessment or certification.
2.1, 1st sentence		Not covered.
2.1, bullet 1		Not covered.
2.1, bullet 2	4.2	Covered. EN ISO 13485 requires that the quality management system documentation includes information on the device(s) within its scope.

SOURCE: EN ISO 13485:2016+A11:2021

Harmonised

EUROPEAN COMMITTEE FOR STANDARDIZATION

Presumption of conformity to the legal requirements of a regulation (e.g., MDR) by demonstrating compliance to a harmonised standard

Using an unharmonised standard requires explanation of compliance rationale in technical documentation

CENELEC

Need a published Standardisation Request (mandate) M/575

Agreed on by Member States

Addressed to CEN/CENELEC

Create Annex Z crosslink table
- Informative but provides legal clarity
- Covered, partially covered, not covered

Manufacturer identifies & implements additional actions to cover these requirements

See MDCG 2021-5: *Guidance on standardisation for medical devices*

International Standards

International consensus standards such as those developed by ISO or IEC are preferred because they are crowd-sourced from experts around the world

They are consensus-developed in a transparent and inclusive manner, which means that these standards reflect an agreement across borders

- Their technical content is best suited to ensure patient and public health, state of the art technology & thinking, and best practice

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US FDA Recognition

Process of identifying standards that medical device manufacturers may submit a declaration of conformity to demonstrate relevant requirements in the FD&C Act have been met

- FDA may recognize all, part, or none of a consensus standard
- Any interested party may submit a request for recognition to the FDA
- Recognition Number is assigned
- 'Supplemental Information Sheet' is provided

Recognized Consensus Standards: Medical Devices

FDA Home › Medical Devices › Databases

1 result found
Standards Designation Number: *14971*

Results per Page 100

New Search | Export To Excel | StandardsSearchAssistance

Date of Entry	Specialty Task Group Area	Recognition Number	Extent of Recognition	Standards Developing Organization	Standard Designation Number and Date	Title of Standard
12/23/2019	General I (QS/ RM)	5-125	Complete	ANSI AAMI ISO	14971: 2019	Medical devices - Applications of risk management to medical devices
				ISO	14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices

UK Designated Standards

UK Government designates standards for conformity with UKCA marking (or similar) legislation

Contains National Foreword and may contain a National Annex, showing correlation between standard and the relevant UK legislation, e.g., UK Medical Devices Regulation S.I. 2002

- 'Similar' annex to European Annex Z
- Dependent on new UK medical device regulation that has yet to be published as a S.I.
- Work in progress…

National Annex NZ
(informative)

Relationship between this British Standard and the Conformity Assessment Requirements of the Medical Devices Regulations 2002 (S.I. 2002 No. 618, as amended) (UK MDR 2002) aimed to be covered

This British Standard may be used to provide voluntary means of conforming to particular requirements of the UK MDR 2002 ('the Regulations'), as amended.

Once this standard is cited in the official designated standards list for medical devices, compliance with the normative clauses of this standard given in Tables NZ.1, NZ.2 and NZ.3 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding conformity assessment requirements stated in the annexes of Directives 90/385/EEC on active implantable medical devices, 93/42/EEC on medical devices and 98/79/EC on in vitro diagnostic medical devices as referred to by the Regulations as shown in the tables.

SOURCE: BS EN ISO 13485:2016+A11:2021

Designated, Harmonised, Recognized…

Neither designation, harmonisation nor recognition are automatic

Additional standards will be designated, harmonised and/or recognised in the future

They simplify process for demonstrating conformity to legal requirements in respective jurisdictions

Annex NZ only found in UK (BSI) versions

Annex Z only found in EN versions

Recognition only applies for US FDA purposes

Potential Risks & Hurdles?

National/regional pressures to modify/create local versions of standards can lead to an array of divergent versions

These pressures arise from:

- Time taken to make changes
- Different regulatory requirements
- Diverging views on state of the art & best practice

This can obviate the benefits of relying upon the original consensus **international standards** in global commerce

These regional pressures can result in unintended consequences:

- Failure for regulatory jurisdictions to designate/harmonise/recognize standards
- Different requirements for the same device leading to duplicative devices and lack of interoperability

Can lead to a global breakdown of uniform technical standards

Many European standards are adoptions of international standards from ISO and IEC

Intent is to *harmonise* many standards via Standardisation Request, M/575

Many US standards are adoptions of international standards from ISO and IEC

Intent is to *recognize* many standards via FDA's Recognized Consensus Standards Program

Changes to the main text of these standards in order to make them acceptable for regulatory purposes could have consequences for global alignment if these changes are not globally acceptable to the core **international** document

European Union Regulatory Changes

Since the early 1990s, there was stability in the legal status of medical devices

- 93/42/EEC (MDD), 90/385/EEC (AIMDD)

UNTIL the European Medical Device Regulation, 2017/745 (MDR), was enacted in 2017 with a three-year transition

- extended in 2023

The transition to the MDR means many European standards harmonised to the former MDD and AIMDD need now to be harmonised to the MDR

The European Commission's Standardisation Request, M/575, lists 201 standards that need modification to be harmonised

- deadline of May 2024, expected to be extended to May 2028
- Currently, we have 16 standards harmonised to the MDR (and 10 standards to the IVDR)

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Changes to standards are needed to align with the different MDR requirements

- Need to address sustainability?

This may require:

- Changes to the technical content of the standard
- Minor amendments to a standard's European annexes and/or European foreword addressing the presumption of conformity

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Where changes are needed to the core text of the standard, this requires a new edition

- in this instance, if the standards are European adoptions of **international standards**, these modifications must be consensus-accepted by ISO or IEC in order to maintain global alignment
- If these changes are not acceptable at ISO/IEC, we could be faced with a European standard that differs from the **international text**

In a worst-case scenario, standards with almost identical title, scope and content could exist as **different regional and international standards**

For globally marketed products, what will this look like?

US Standards & the Future

In order for a document to be acceptable for regulatory purposes (FDA) and ultimately FDA recognition, an ISO or IEC document may not be adopted as a US national standard with identical ISO or IEC text

This can result in the document being published as a US national standard with national deviations

The standard will have same standard number, but a different prefix

- For example, ISO 15883-1 versus ANSI/AAMI ST15883-1

Opportunities for confusion by standards users:

- Regulators
- Manufacturers
- End users
- Standards developers

Use of Standards - Summary

Designated (UK)

- UK process to support UKCA marking
- Process still being developed
- Currently designated to Medical Device Regulations 2002
  - 276 medical device standards

Harmonised (EU)

- EU process to support CE marking
- Harmonised to MDR and/or IVDR
- 250 standards requested for harmonisation by 2024/2028
- Annex Z identified as +A11:2021
- Maps the GSPR of the regulations and how they are covered by the clauses and subclauses of the standard

Recognised (US)

- US process for declaring conformity to regulations
- Supplemental Information Sheet (SIS) – recognition number, extent of recognition, transition period for standard, rational for recognition
- No alignment/relationship to regulation provided other than ‘Extent of Recognition’ in SIS

Medical Device Law

>27,000 medical device manufacturers globally

- Largest medical device markets – US, EU and Japan
- Growing markets – China, South Korea, India and Israel

US Federal Food, Drug, and Cosmetic Act (1938), Amended in 1962 & 1976

- Established a regulatory framework for medical devices in the US
- Created US FDA Center for Devices and Radiological Health (CDRH)
- Demonstrate safety & effectiveness of devices

Japan - Regulation for medical devices (1945)

- Updated in 2014 – Pharmaceuticals and Medical Devices Act (PMDA)

Medical Device Law

Australia – Therapeutic Goods Act (1989)

- 2021 – new IVD regulations

EU Medical Devices Directives (1993)

- Separate directives for MD, IVDD and AIMD
- Replaced by Medical Device Regulation 2017/745 and In Vitro Device Regulation 2017/746

Canadian Medical Device Regulations (1998)

- Outline the requirements for medical device licensing, labelling, and post-market surveillance

European Standards

Presumption of conformity

Use of standards (harmonised or not) is still voluntary

Harmonised standards = benchmark to evaluate manufacturer's compliance to the legislative requirement

However…

Annex VII, 4.5.1 of MDR/IVDR - "The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, **even if the manufacturer does not claim to be in compliance"**

The Future…

- Where changes are needed to the core text of the standard, this usually results in a new edition
  - Where standards are adoptions of international standards, **these modifications must be made at ISO or IEC level** and consensus-accepted in order to maintain global alignment
- It is unrealistic to expect exact alignment of global regulations for medical devices, but standards should be drafted to allow for:
  - alignment to the different regulatory jurisdictions
  - serve as state of the art if recognized/harmonised
  - serve as state of the art if the most recent edition
- National or regional annexes help by providing correlation to local legal requirements WITHOUT regional or national changes to the core text

Standards Suitable for Regulatory

When drafting a new standard, or a revision to an existing standard, the following are always considered:

- Application of the applicable CEN/CENELEC or ISO/IEC drafting rules
- Consensus agreement
- Development stages

What is often not considered:

- Applicable global regulations and means to address their requirements
- Caution when drafting very specific requirements that may not be globally acceptable
- Drafting of a single requirement per clause or subclause
- Means for the standards user to easily demonstrate conformity to the standard

IMDRF has specific recommendations for incorporating *Essential Principles* into standards development[7]

7. IMDRF – Optimizing Standards for Regulatory Use, 2018

Conclusion

To facilitate global harmonization, any change to a consensus-developed standard should be considered an improvement to its technical content or to its utility for regulatory purposes

All actors involved in the preparation, implementation and use of standards should be aware of the global consequences of these actions, however well intended

Global alignment of the technical content of **international standards** benefits the standard user by:

- simplifying conformity with regulatory requirements
- reducing costs
- ultimately improving patient safety.